Nos. 2017-1480

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC.; AMGEN MANUFACTURING LIMITED; AMGEN USA, INC.,

Plaintiffs-Appellees,

v.

SANOFI; AVENTISUB, LLC; REGENERON PHARMACEUTICALS INC.; SANOFI-AVENTIS U.S., LLC,

Defendants-Appellants.

Appeal from the United States District Court for the District of Delaware, Case No. 1:14-cv-01317-SLR.
The Honorable **Sue L. Robinson**, Judge Presiding.

MOTION OF AMICI CURIAE DR. LUIS APARICIO, MD; DR. W. ROSS DAVIS, MD; DR. AVICHAI ERES, MD; DR. NORMAN LEPOR, MD; DR. MARY McGOWAN, MD; DR. NARENDRA SINGH, MD; DR. PAUL THOMPSON, MD; ROSA DEBERNARDO; AND ALINA WILSON FOR LEAVE TO FILE AMICUS CURIAE BRIEF

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for the *Amici Curiae* certifies the following:

1. The full name of every party or amicus represented by me is:

Dr. Luis Aparicio, MD; Dr. W. Ross Davis, MD; Dr. Avichai Eres, MD; Dr. Norman Lepor, MD; Dr. Mary McGowan, MD; Dr. Narendra Singh, MD; Dr. Paul Thompson, MD; Rosa DeBernardo; and Alina Wilson.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amici now represented by me in the trial court or agency or are expected to appear in this court are:

Boies, Schiller & Flexner LLP: William D. Marsillo and Michael D. Jay.

Pursuant to Federal Circuit Rule 27(a)(5), counsel for amici curiae contacted counsel for the parties to ascertain whether the parties would consent or oppose this motion. Appellants do not oppose the motion and do not intend to file a response. Appellees oppose the motion and intend to file a response.

MOTION FOR LEAVE TO FILE AMICI CURIAE BRIEF

Pursuant to Rule 29 of the Federal Rules of Appellate Procedure, Dr. Luis Aparicio, MD; Dr. W. Ross Davis, MD; Dr. Avichai Eres, MD; Dr. Norman Lepor, MD; Dr. Mary McGowan, MD; Dr. Narendra Singh, MD; Dr. Paul Thompson, MD; Rosa DeBernardo; and Alina Wilson respectfully request leave of this Court to file their brief in support of Defendants-Appellants.

Amici Curiae comprise two hypercholesterolemia patients successfully treated with Praluent® ("Praluent") whose interests are in being able to continue with this potentially life-saving therapy and physicians who currently use Praluent to treat patients and whose interests are solely to provide their patients with the best medical care possible.

Rosa DeBernardo is an 84-year-old grandmother with severe hypercholesterolemia who has been successfully treated with Praluent since shortly after Praluent became available on the market. In that time, Praluent has been a life-saving therapy for Ms. DeBernardo: her low-density lipoprotein cholesterol level (LDL-C) has dropped to nearly one-third of the dangerously-high level that persisted when she started the therapy. Prior treatment efforts using statins and other therapeutics did not effectively reduce her LDL-C level. In addition, given Ms. DeBernardo's allergy to latex, Praluent is the only PCSK9 antibody treatment protocol available to her, as it is the only PCSK9 antibody preparation that does not contain latex. Exposure to latex can cause a severe allergic reaction. If Praluent is removed from the market, Ms. DeBernardo will be significantly and irreparably harmed. Accordingly, she believes that the district court's permanent injunction affecting Appellants' ability to manufacture and distribute Praluent should be vacated.

Alina Wilson is a woman in her early forties with familial hypercholesterolemia who has seen dramatic reductions in her cholesterol levels since she started taking Praluent just ten months ago. Familial hypercholesterolemia is a genetic mutation that leads to elevated LDL-C from birth and those affected are among the highest risk of developing coronary artery disease at a young age. Ms. Wilson had tried countless other therapies over her lifetime, but none were ever effective enough to reach LDL-C levels recommended by the American Heart Association and American College of Cardiology. Her high cholesterol levels led to heart disease, and last year Ms. Wilson had quadruple bypass surgery and suffered a heart attack while recovering from her surgery. She started on Praluent just shortly thereafter, and her LDL-C level is now less than half what it was prior to starting Praluent. If Praluent is removed from the market, Ms. Wilson will be significantly and irreparably harmed. Accordingly, she believes that the district court's permanent injunction should be vacated.

Dr. Luis Aparicio, MD is a board-certified pediatric endocrinologist who specializes in treating patients with a variety of endocrine disorders and diabetes, a cardiovascular equivalent, often in the context of other debilitating diseases. In his current role at Metabolic Disease Associates, Dr. Aparicio oversees the care and treatment of a number of patients taking Praluent.

Dr. W. Ross Davis, MD is a cardiologist at Advanced Cardiovascular LLC ("Advanced Cardiovascular") in Auburn, Alabama. Through his affiliation with Advanced Cardiovascular, Dr. Davis currently treats a host of patients with often hard-to-treat high cholesterol levels, routinely utilizing one of two monoclonal antibody treatment protocols, Praluent and Repatha® ("Repatha").

Dr. Avichai Eres, MD is a cardiologist at Kentucky Cardiology and the Director of the Heart Catheterization Laboratory at Saint Joseph East Hospital, both in Lexington, Kentucky. Through his affiliation with these facilities, Dr. Eres routinely treats patients with difficult-to-treat high cholesterol levels using Praluent and Repatha.

Dr. Norman Lepor, MD is a cardiologist in private practice at the Cedars-Sinai Heart Institute in Los Angeles, California. In his practice, Dr. Lepor regularly treats patients with difficult-to-treat high cholesterol levels using Praluent and Repatha.

Dr. Mary P. McGowan, MD is a lipid expert who treats patients with a variety of lipid disorders, in her capacity as co-director of the Dartmouth-Hitchock Lipid Clinic at the Dartmouth-Hitchcock Heart & Vascular Center in Lebanon, New Hampshire. She is also Chief Medical Officer at Esperion Therapeutics.

Dr. Narendra Singh, MD is a cardiologist and the Director of Clinical Research at Atlanta Heart Specialists, LLC. He has prescribed PCSK9 inhibitors, including Praluent, to dozens of patients in his private practice, and these therapies have been extremely effective for his patients.

Dr. Paul Thompson, MD is Chief of Cardiology at Hartford Hospital in Hartford, Connecticut. In his capacity as Chief of Cardiology, Dr. Thompson often relies on PCSK9 inhibitors, including Praluent, as an effective and life-saving treatment for his patients.

Dr. Aparicio, Dr. Davis, Dr. Eres, Dr. Lepor, Dr. McGowan, Dr. Singh, and Dr. Thompson (collectively, the "amici physicians") believe that if Praluent is removed from the market, the result will be a significant disruption in their cardiovascular care of a large number of their patients. These patients will be significantly and irreparably harmed, including by being exposed to an unnecessarily increased risk of adverse health effects that will endanger their lives.

Accordingly, the amici physicians believe that the district court's permanent injunction affecting Appellants' ability to manufacture and distribute Praluent should be vacated.

Amici's views on the impact of removing Praluent from the market are desirable and relevant to the Court in considering the impact of the district court's permanent injunction on the public interest. Rule 29 requires that an amicus state its "interest" and provide reasons why its brief is "desirable" and "relevant to the disposition of the case." Fed. R. App. Pro. 29(a)(3)(B); *see also Fluor Corp. & Affiliates v. United States*, 35 Fed. Cl. 284, 285 (1996) ("When a court's decision would directly affect a person or entity's rights or would set a controlling precedent regarding a claim of that person or entity, leave to file an amicus curiae brief may be allowed."). Motions for leave should be granted "unless it is obvious that the proposed briefs do not meet Rule 29's criteria as broadly interpreted." *Neonatology Associates, P.A. v. C.I.R.*, 293 F.3d 128, 133 (3d Cir. 2002) (granting leave over opposition). Here, amici can provide this Court with unique, first-hand perspectives on the effect that removing Praluent from the market would have on their lives, the lives of their patients, and on the lives of others similarly situated. To the extent this Court must weigh the public interest and various other interests in deciding whether to affirm or vacate the injunction in this case, there can be no more relevant or useful information than amici's perspectives.

In addition, amici's brief will not burden the Court or the parties and will not interfere with the orderly presentation and review of the arguments. Appellees have indicated that they intend to respond to this motion. Appellees, however, have no legitimate basis to oppose amici's brief and certainly cannot purport to assert any prejudice that can outweigh the prejudice to amici if their significant input is not considered.

Finally, this Court regularly grants motions to file amicus briefs that are relevant to the disposition of the case. *See, e.g., Tivo, Inc. v. Echostar Corp.*, 2009 WL 1939175 at *1 (Fed. Cir. July 1, 2009); *Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation, Limited Partnership*, 2000 WL 1300430 at *1 (Fed Cir. Sept 1, 2000); *Kearns v. Chrysler Corporation*, 1993 WL 452257 at *1 (Fed. Cir. September 22, 1993).

Accordingly, amici respectfully requests that the Court grant them leave to file the accompanying amici curiae brief.

Dated: February 24, 2017

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) and 32(a)(7)(B). The brief contains 1,307 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Office Word in 14-point Times New Roman font.

Dated: February 24, 2017

/s/ William D. Marsillo

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CERTIFICATE OF SERVICE

I hereby certify that on February 24, 2017, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: February 24, 2017

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